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July 23, 1999

Dockets Management Branch
(HFA - 305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

RE: Federal Register Vol. 64, No. 93 Friday, May 14, 1999
Foreign Establishment Registration and Listing.

Medical Devices Canada is a national trade association representing the medical devices industry in Canada. Several of our members export medical devices to the United States and therefore, under the terms of the proposed amendment described in the above mentioned FR, they would be considered foreign establishments.

MEDEC does not object to the requirement for foreign establishments to register with the US FDA. In fact, under Canada's device license requirements, manufacturers, both foreign and domestic, are essentially registered with Health Canada. MEDEC recognizes the desire of FDA to establish a database of foreign establishments exporting medical devices to the US.

MEDEC does find objectionable, however, the requirement to designate a United States Agent for purposes of importing a medical device into the US. The responsibilities of the US agent described in the proposed amendment would include submitting medical reports, annual certifications, registration and listing information as well as premarket notifications, in addition to acting as official correspondent.

Canadian manufacturers would likely have to employ firms that act as designated agents, and firms of this calibre would likely charge substantial fees for their services. Whereas most Canadian manufacturers exporting to the US employ distributors to sell their products, it is unlikely they would employ these same distributors to act as the US agent since they (distributors) would be privy to confidential information required of the agent.

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US agents would presumably be liable for their actions and accountable to the FDA which naturally would add to the cost of doing business (liability insurance) and translate into substantial fees for services rendered. This type of situation currently exists in other countries, e.g., Japan and Europe whereby so-called designated agents offer their services for a fee.

The requirement for a US agent may also impart a disadvantage to Canadian companies doing business in the US since Canada has no reciprocal requirement. Canadian manufacturers selling into the US would be required to expend considerable costs in maintaining a US designated agent whereas US manufacturers selling into Canada do not. Also, US manufacturers selling in the US would have a significant competitive advantage since they would not have to employ a special agent.

The requirement for a US agent also will, in our opinion, add one more obstacle to communications between FDA and Canadian manufacturers. This will only add to delays and slow down rapid exchange of information should that be required.

MEDEC responded to the Federal Register Notice July 23, 1996, Medical Devices; Reporting; Certification and U.S. Designated Agents; and at that time, submitted the following comment relative to the US Agent which we believe is still applicable to the current proposal:

> *"Canadian manufacturers are concerned with implementation issues surrounding the Designated Agent requirement. The U.S. Designated Agent will be liable for the tasks to be performed and this will surely result in extremely high fees that many companies may not be able to afford. Confidentiality is also a concern. The Designated Agent may have little experience or expertise in performing those tasks, which would leave Canadian manufacturers with a high degree of concern regarding the agent's ability to carry out the tasks in a timely and accurate manner. In fact, any Designated Agent will not have the expertise of the original manufacturer."*

The FDA does not appear to have addressed this potential impact in its estimated annual reporting burden. The issue for Canadian manufacturers is not the increased burden of paperwork in filing establishment registrations, rather it is the significant economic impact of employing a Designated Agent.

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If FDA is concerned with communications and/or the ability to communicate with a foreign manufacturer, albeit a legitimate concern, it should be less of a problem with Canadian manufacturers. Canada and the US share many similarities that facilitate communications between manufacturers and FDA. Language, culture, business ethics, time zones, communications capabilities, are essentially on a par between both countries.

The proposed amendment stipulates a US agent will be responsible for submitting documents such as premarket notifications. We presume this responsibility is a desire to facilitate communications between FDA and the foreign establishment. However, should communications between FDA and Canadian manufacturers be optimal, the designated agent requirement might not be necessary.

We suggest that the amendment be promulgated to require foreign establishment registration but that the US Agent requirement be implemented based on the likelihood of communication problems with certain regions. Regions that would not present a problem could be exempt from this particular requirement. FDA might also consider staying the US Agent requirement with countries where there is not a reciprocal requirement.

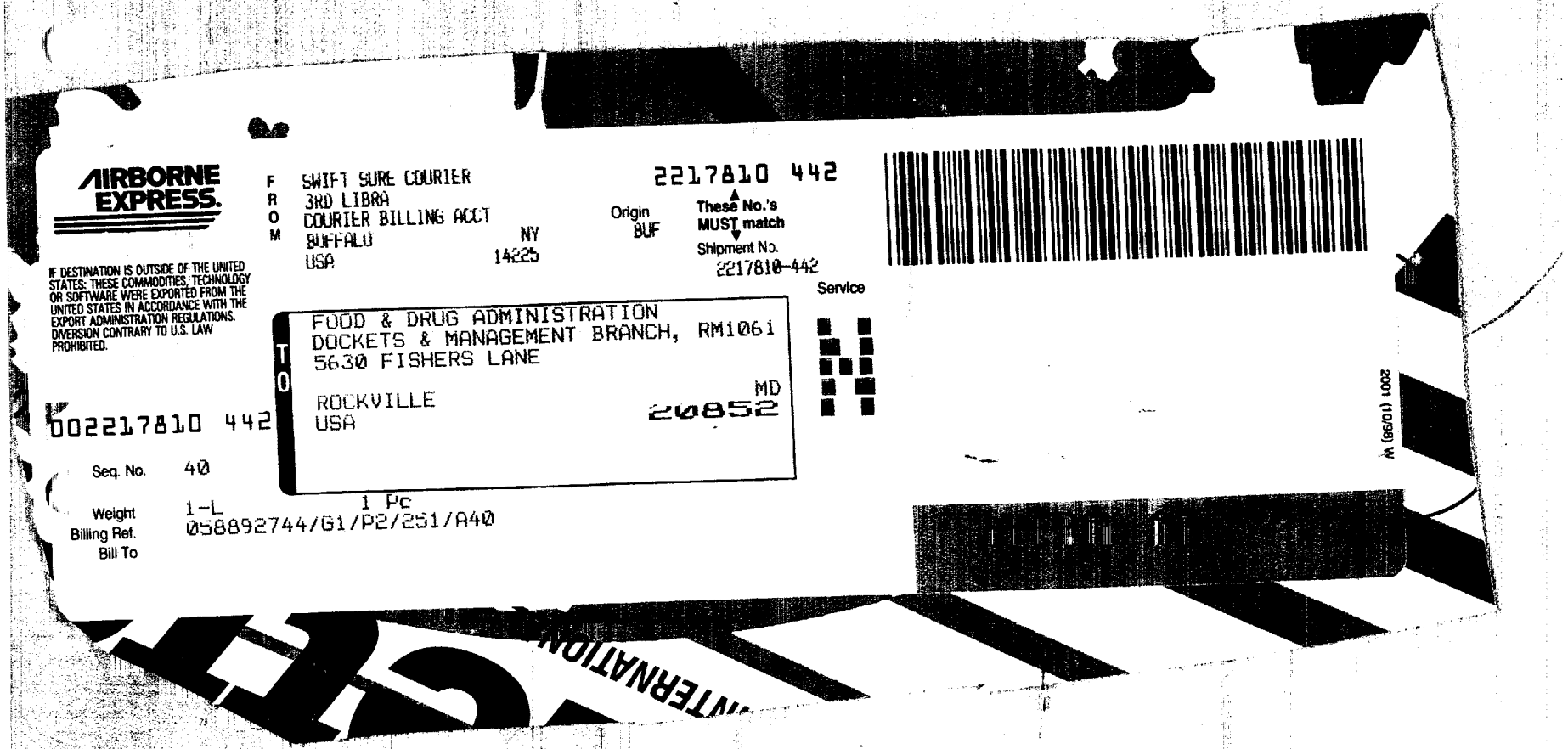
Alternatively, we suggest a dialogue between FDA and Health Canada to explore co-operative measures between the two countries. Such discussions could lead to reciprocal understandings to satisfy FDA's concerns with Canadian manufacturers.

We trust these comments will be taken under consideration and eagerly await the decision of the FDA on this proposed amendment.

Sincerely,

Kevin Murray
Director, Regulatory Affairs

cc. Beth Pieterson, Health Canada
David Shortall, Dept. Foreign Affairs Int'l Trade
Linda Leinan, Industry Canada
Birgit Matthiesen, Embassy of Canada, Washington



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